UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/698,121	10/30/2000	Jerome Aucouturier	746200-000062	5877

21967 7590 07/07/2003

HUNTON & WILLIAMS
INTELLECTUAL PROPERTY DEPARTMENT
1900 K STREET, N.W.
SUITE 1200
WASHINGTON, DC 20006-1109

EXAMINER
EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
1644	4

DATE MAILED: 07/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/698,121	Aucouturier et al.
Examiner	**Art Unit**
G.R. Ewoldt, Ph.D.	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Apr 23, 2003*

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *19, 20, and 30-33* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideratio

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *19, 20, and 30-33* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examine

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicant's Amendment and Remarks, filed 4/23/03, are acknowledged

2. Claims 19-20 and 30-33 are being acted upon.

3. Applicant is advised that the previous Action, mailed 1/23/03, was not made final. Note that the Action itself nowhere indicated that it was final, however, due to a typographical error, the Office Action Summary, PTO-Form 326, did indicate that the Action was final. The Examiner apologizes for any confusion.

4. Note that Applicant has introduced a number of new species into the claims. Applicant is advised that the application has been examined only as it recites the chosen species of "Composition h, mannitan oleate (8EOs)".

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 19-20 and 30-32, and newly added claim 33, stand/are rejected under 35 U.S.C. 102(b) as being clearly anticipated by U.S. Patent No. 3,678,149 (1972), for the reasons of record set forth in Paper No. 18, mailed 1/23/03.

Applicant's arguments, filed 4/23/03, have been fully considered but they are not persuasive. Applicant argues that "the use of mannitan oleate is clearly distinguished from the claims of the present invention. The present invention does not involve mannitan oleate. Rather, the present invention involves *polyethoxylated* mannitan oleate."

It is the Examiner's position that the brief disclosure of the specification does not sufficiently distinguish the chosen species of mannitan oleate from the mannitan oleate of the references to render the instant "method"/"process" patentably distinct. Note that Applicant's argument comprises nothing more that an attorney's assertion that the claimed method is not the method of the prior art. An attorney's argument cannot be

considered evidence unless it is an admission, in which case, an examiner may use the admission in making a rejection. See MPEP § 2129 and § 2144.03 for a discussion of admissions as prior art. Additionally, the arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness."). See MPEP § 716.01(c) for examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration MPEP 2145.

Also note that "mannitan oleate", such as that taught by the references, most likely comprises a number species of mannitan oleates, see O'Neill et al., (Table II, 1972). Applicant has not shown that the specification as filed can differentiate the species of the claimed method from the multiple species of the method of the prior art.

7. Claims 19-20 and 30-32, and newly added claim 33, stand/are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Perlaza et al. (1998), for the reasons of record set forth in Paper No. 18, mailed 1/23/03.

Applicant's arguments, filed 4/23/03, have been fully considered but they are not persuasive. Applicant has not traversed this rejection separately. See the Examiner's response in section 6 above.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 19-20 and 30-32, and newly added claim 33, stand/are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record set forth in Paper No. 18, mailed 1/23/03.

Applicant's arguments, filed 4/23/03, have been fully considered but they are not persuasive. Applicant argues that the instant amendments obviate the instant rejection in that they more clearly point out the claimed subject matter.

It is the Examiner's position that the claims remain indefinite in that they recite a method that fails to recite adequate method steps. Note that method (or process) claims must recite appropriate method (or precess) steps. Regarding Claim 19, the claim recites a method of "providing". In the instant context, to provide is to supply or make ready. The only additional verb in the claim is "combining". In the instant context, to supply or make ready by combining two agents does not comprise a patentable method. The impropriety of Claim 32 is more readily apparent. The claim recites a process "for enhancing the immune response". The only verb other than enhancing in the claim is again, "combining". Thus, the claim recites a method of enhancing a response simply by combining two agents. At minimum, a process "for enhancing the immune response" would require a method step that could lead to the claimed induction, e.g., administration to a subject, thus, inducing the claimed immune response. As currently recited, the format of the claims is such that the claims reciting the term "method" or "process" appear to actually more closely read on the product being employed in the claimed method.

10. The following is a new ground for rejection necessitated by Applicant's amendment.

11. Claims 19-20, 30-31 and 33 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, specifically, the recitation in Claims 19 and 33 of the term "OE" is vague and indefinite as the term is not defined in the specification.

12. No claim is allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing

date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805 The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 at 703-872-9306 (before final) and 703-872-9307 (after final).

G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600
July 02, 2003